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RC  
07-29-97  
5-225E

SERIAL NUMBER	REQUEST DATE	FIRST NAMED APPLICANT	ATTORNEY DOCKET NO.
P-92,677	7/11/97	LIN, ET AL	S -225 CASE FAMIL

Title: **GLIAL CELL LINE-DERIVED NEUROTROPHIC FACTOR**

Art Unit	Paper Number
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Licensee under 35 U.S.C. 184 is hereby granted to file in any foreign country a patent application and any amendments thereto corresponding to the subject matter of this U.S. application identified above and/or any material accompanying the petition. This license is conditioned upon modification of any applicable secrecy order and is subject to revocation without notice.

License Number: 516,617  
Grant Date: 18-Jul-97

This license is granted retroactively to the date(s) and the country(s) indicated on the attached decision.

Approved:

  
for Commissioner of Patents and Trademarks

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This license does not empower the filing of any applications, amendments, supplements or continuances originating in this country which disclose inventions, modifications, or variations not disclosed in the subject matter identified above.

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### LICENSE FOR FOREIGN FILING

[Title 35, United States Code (1952) Sections 184, 185, 186]



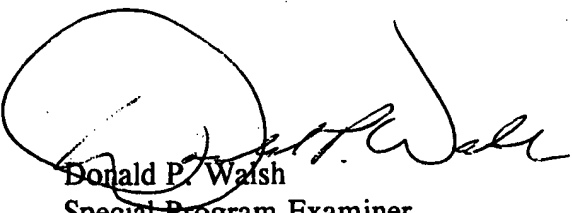
UNITED STATES DEPARTMENT OF COMMERCE  
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Ex parte: Lin, et al. : DECISION ON REQUEST  
P-Number: 92677 : FOR RETROACTIVE LICENSE  
Request Filed: July 11, 1997 : UNDER 37 CFR 5.25

Title: GLIAL CELL LINE-DERIVED NEUROTROPHIC FACTOR

In view of the above identified communication, it has been determined that a retroactive license for foreign filing under 35 U.S.C. 184 be granted only with respect to the filing(s) listed below. The petition complies with 37 C.F.R. 5.25 in that there is an adequate showing that the subject matter in question was not under secrecy order, that the license was diligently sought, and that the material was filed abroad without the required license under 37 C.F.R. 5.11 first having been obtained through error and without deceptive intent.

<u>Country</u>	<u>Date</u>
PCT/US92/07888	9/17/92
Bahamas (1053)	9/18/92
Israel (103223)	9/18/92
Mexico (92 5293)	9/17/92
New Zealand (244392)	9/18/92
Philippines (44956)	9/18/92
South Africa (92/7159)	9/18/92
Taiwan (81108487)	10/23/92
Portugal (100879)	9/18/92

  
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(703) 306-4173

PLEASE STAMP TO ACKNOWLEDGE RECEIPT OF THE FOLLOWING:

Applicants: Lin, et al.

For: GLIAL CELL LINE-DERIVED NEUROTROPHIC FACTOR

Docket No.: S-225 Case Family

(see Serial No.: 08/182,183; filed May 23, 1994:

Docket No.: S-225E)

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Enclosed:

1. Petition For Retroactive Foreign Filing License transmittal
2. Petition for Retroactive License Under 35 U.S.C. §184
3. Declaration of Daniel R. Curry
4. Declaration of Barry J. Swanson
5. Copy of publication (WO 93/06116) of International  
Application Number PCT/US92/07888
6. Copy of Petition for Retroactive License Under 35 U.S.C. §184

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Date: July 11, 1997

Case Ref.: S-225 case family

CEVanHorn/clw (Drop 701)

**HAND CARRY**

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8/1/97

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants: Lin, et al.

For: GLIAL CELL LINE-DERIVED NEUROTROPHIC FACTOR

Docket No.: S-225 Case Family  
(see Serial No.: 08/182,183; filed May 23, 1994; Docket No.:S-225E

#34 1/2

DECLARATION REGARDING PETITION FOR RETROACTIVE LICENSE  
UNDER 35 U.S.C. §184 (37 C.F.R. §5.25)

Assistant Commissioner of Patents  
Washington, D. C. 20231  
Attention: Licensing and Review

Sir:

**Declarant**

I, Barry J. Swanson (Declarant), am the former Attorney for Applicant of this family of applications.

**Statement**

As local counsel for Applicants at the time of the foreign filings described in the accompanying petition for retroactive foreign filing license, Declarant handled patent matters concerning the cases in the designated countries in conjunction with foreign counsel.

The application prepared for the PCT filing, which application was also used in the national filings described in the Petition (paragraph 5), included the following information which was not contained in Application No. 07/788,423 (S-225B) for which a foreign filing license had been granted:

- Example 1 -- further information concerning lack of enhancement of serotonin uptake by serotonergic neurons
- Example 2 -- further information concerning the nucleotide sequence encoding the first 50 amino acids of leader (pre-pro) sequence

- Example 6 -- a protein refolding process and information concerning an updated method of enhancing E. coli production
- Figures 22-28 illustrating data concerning the above
- further information concerning uses for GDNF
  - Example 7 manufacture of antibodies -- using known techniques
  - Example 8 encapsulation and implantation of GDNF producing cells -- using known techniques

This supplemental information to Examples 1, 2 and 6 was provided to describe the latest information concerning neuron populations affected or not affected by the GDNF proteins, further information on the sequencing of the nucleotides encoding the leader sequence of the GDNF proteins, and the latest best mode information concerning E. coli production of the proteins. The supplemental information exemplified by Example 7 concerned the latest information involving the production of anti-GDNF antibodies using the GDNF proteins described in the parent applications. The supplemental information exemplified by Example 8 concerned the envisioned use of encapsulated and implanted GDNF producing cells as based on teachings in the art further described on page 42, line 9 through page 43, line 11. This information was included in the PCT filing because the filing also designated the United States.

Declarant's general practice was to obtain the grant of a foreign filing license prior to filing an application outside the United States or to have the parent application on file for a period of not less than six months prior to the foreign filing. Due to the unique circumstances of the present case, however, the grant of a foreign filing license was overlooked. The unique circumstances included the fact that the parent applications were among the first patent applications assigned to a newly formed venture, the Syntex-Synergen Neuroscience Joint Venture.

The joint venture was formed in February of 1990 by Syntex (U.S.A.), Inc. of Palo Alto, California and Synergen, Inc. of Boulder, Colorado. The parent applications were the first patent applications filed by the joint venture, and the foreign cases involved in the accompanying petition were the first foreign applications filed by Declarant on behalf of the joint venture. Declarant was working closely with in-house patent counsel at both Syntex and Synergen in the preparation and filing of the foreign applications. The joint venture, however, had no defined procedures or checklists for confirming that all formalities and filing requirements were met. Thus, no counsel was identified as responsible for a final determination that all filing requirements, including foreign filing requirements, had been met. As a result, Declarant failed to consider whether a foreign filing license had been obtained for the application that was foreign filed.

In addition, the present case was unique in the number of parent cases involved. As described in the accompanying petition, a foreign filing license had been granted for the third

application in the series, and it was not typical in my office to have more than a single parent application involved in a foreign filing. Moreover, supplemental information for inclusion in the foreign filed application was received only a few weeks prior to the one year deadline for foreign filing. This further deviated from the norm as typically there were no continuation in part filings made to cases more than six months after the earliest filing date. The numerous parent cases and the late submission of information from the joint venture also led to Declarant's failure to consider whether a foreign filing license had been obtained prior to forwarding materials to foreign counsel for filing.

As a result of these circumstances, Declarant mistakenly overlooked the need to obtain a further foreign filing license (in addition to that granted for Application No. 07/788,423 (S-225B)) due to the inclusion of the supplemental information. Had Declarant considered the need for an additional foreign filing license grant, Declarant would have filed a petition for an expedited license. The mistake, however, was an error through overlooking the need for any additional license grant. The foreign filing was not performed with any deceptive intent.

Thus, Declarant as counsel for Applicants at the time of the foreign filings verifies that there was no plan or design to circumvent the statutes in question by providing the material to foreign counsel for filing abroad or by performing the foreign filings. The failure to obtain a foreign filing license prior to filing abroad was through error and without deceptive intent.

I further declare that all statements made herein of my own knowledge are true, that all statements made on information and belief are believed to be true, and that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both (18 U.S.C. 1001), and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

Respectfully submitted,



Barry J. Swanson

Registration No: 33,215

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Date: July 8, 1997